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(54) Catheter for extracorporeal treatment.

(57) A dual lumen catheter (100) is disclosed for providing extracorporeal treatment such as hemodialysis, which is percutaneously inserted for either short-term or long-term vascular access. The catheter includes a main body (101) having proximal and distal segments connected to a pair of clamping limbs (104,105) via a manifold (106). The distal segment (102) includes two tubular members (201,202) laterally attached to each other, one of which is thinner than the other and collapsible for inserting the catheter through a much smaller diameter peel-away sheath. Contrary to existing practices, the lengths of the arterial and venous tubular members are reversed such as to provide a longer negative pressure intake lumen. A hydrophilic slip coating (207) covers the distal segment (102) to further ease the insertion of the distal segment into the peel-away sheath. The cross-sectional area of the proximal segment (103) is generally elliptical shaped for providing a leak proof fit through the vascular access site. A ring-like grommet (116) moveable along the proximal segment anchors the catheter to the surrounding tissue. The lumens extending throughout the entire catheter are generally circular in nature and substantially equal in cross-sectional area to provide substantially equal flows of intake and return blood and to minimize clotting. The wall thickness of the negative pressure intake member (204) is approximately one and a half to three times as thick as that of the tin-walled positive pressure tubular wall (206) to maintain adequate flows of blood without collapsing or stretching.

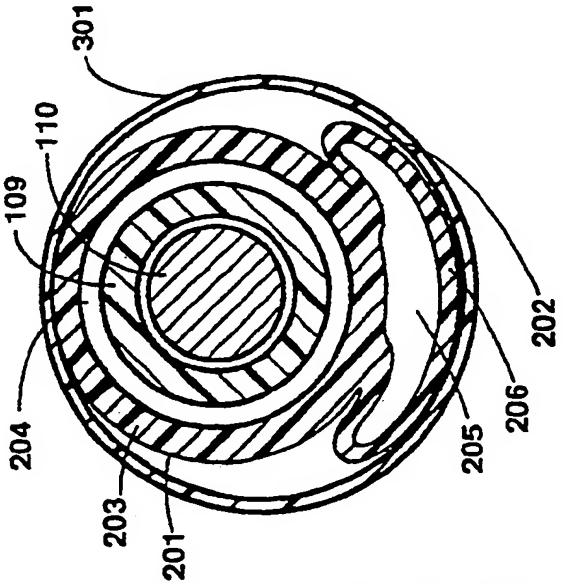

Fig. 3

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hemodialysis and the like. This vascular access catheter is percutaneously inserted in a blood vessel, such as preferably the jugular or femoral vein, for either short-term or long-term hemodialysis treatment of the patient. The jugular access site is preferable to the subclavian vein because it is much less likely to cause subclavian vein thrombosis. Subclavian vein thrombosis is a serious long-term disability for a patient on dialysis if it is not diagnosed and successfully treated at an early stage, because it interferes with A-V fistula construction in the ipsilateral arm, leading to a permanently swollen congested arm as long as the fistula is functioning. Internal jugular vein thrombosis is probably not common after internal jugular cannulation, but it causes no disability even if it occurs and is not treated, except that the patient loses a potential access site.

The catheter basically comprises a dual lumen main body 101 attached to a single lumen, arterial clamping limb 104 and a single lumen, venous clamping limb 105 via interconnecting manifold 106. For connection to extracorporeal treatment equipment, two female Luer lock connectors 107 and 108 are connected in a well-known manner to arterial and venous clamping limbs 104 and 105, respectively. The main body of the catheter includes a distal segment 102 and a proximal segment 103 extending proximally therefrom and is comprised of a flexible biocompatible material such as 70 durometer silicon or silastic. Distal segment 102 includes a thick-walled, negative pressure, elongated tubular member 201 and a shorter, thin-walled, collapsible, positive pressure, elongated tubular member 202 attached laterally thereto. The catheter further includes lockable clamps 117 and 118 for clamping arterial and venous clamping limbs 104 and 105, respectively. One such clamp is the BETA-CAP clamp. Qosina slide clamps are also acceptable.

Catheter 100 also includes an anchoring grommet 116 having a ring-like collar 111 positioned around and slideably moveable along proximal segment 103. Flange 112 and 113 extend laterally from the collar and have respective apertures 114 and 115 formed therein to insert sutures therethrough. The grommet is positioned on the proximal segment where it crosses the supraclavicular fossa. Sutures placed through the apertures secure the catheter to the surrounding tissue. The shape of the grommet permits capture of the catheter without compressing it. The smooth rounded flanges allow the grommet to be pulled out with the catheter when it is removed. The anchoring sutures will tear out of the flanges and the only thing left inside the patient will be the sutures themselves.

The overall length of the main body of the catheter from the manifold to the distal tip thereof depends on the insertion site selected by the physician. When inserted in the right jugular vein, the main body of the catheter from manifold to tip is preferably 26cms in length with an 11cms distal segment. For the left jugular site, the main body of the catheter is approximately 30cms in length with the distal segment being 15cms. As suggested, the distal segment 102 includes a collapsible tubular member 202 for inserting the distal segment with stiffening cannula 109 inserted in tubular member 201 over wire guide 110 through a well-known smaller diameter peel-away introducer sheath (not shown). The introducer sheath should be no more than 10cm. in length. This will allow the distal segment to be inserted into the sheath with the distal tip protruding slightly beyond the distal end of the sheath before it is peeled away.

Member 202 is attached laterally to member 201 and collapsible thereon. Member 201 (FIG.2) includes first wall 203 surrounding first longitudinal passageway 204 included therein. This first longitudinal passageway is designated a negative pressure intake lumen for receiving blood from the vessel of a patient for hemodialysis treatment. By way of example, the thickness of first wall 203 is approximately 0.020" with the cross-sectional diameter of passageway 204 being approximately 0.080". The distal end of lumen 204 may be outwardly tapered to prevent clotting and the collection of blood clots thereon. The dimensions of member 201 and lumen 204 allow for blood flow rates of 350-400ml. per minute without collapsing.

Member 202 includes a second longitudinal passageway 205 with second wall 206 positioned thereabout. The thickness of wall 206 is approximately 0.010" with longitudinal passageway having a cross-sectional diameter of approximately 0.080", being approximately equal to that of passageway 204. In an uncollapsed state, the maximum cross-sectional dimension of distal segment is approximately 0.210" plus allowances for fabrication and slip coating 207, which will pass through an 18 French (0.236") aperture. Passageway 205 is designated the positive pressure return lumen for returning blood to the vessel of the patient. The cross-sectional areas of passageways 204 and 205 are substantially equal to provide approximately equal flow rates to and from the patient. The distal segment also includes slip coating 207 which acts as a lubricant to insert the distal segment through the introducer sheath. One such slip coating is a slippery-when-wet hydrophilic coating that is commercially available from Hydromer Inco., Whitehouse, New Jersey. The slip coating is applied to the outside surface of distal segment 102. This hydrophilic slip coating is wetted during the insertion procedure to provide a slippery surface for easier insertion through the peel-away introducer sheath. Furthermore, the presence of blood or other fluids in the introducer sheath further lubricates the collapsed distal segment as it is being inserted therethrough. This further eases the percutaneous insertion of the catheter when inserting a collapsed catheter having

Claims

1. A catheter for extracorporeal treatment, said catheter comprising first (201) and second (202) elongated members, the first elongated member having a first longitudinal passageway (204) therein and a first wall (203) about said first passageway, said first wall having a first predetermined thickness; characterised in that the second elongated member is attached to and collapsible on said first member and has a second longitudinal passageway (205) therein and a second wall (206) having a second predetermined thickness about said second passageway, said first wall thickness being greater than said second wall thickness.

2. The catheter of claim 1, characterised in that said first wall thickness is at least one and a half times as thick as said second wall thickness.

3. The catheter of claim 1, characterised in that said first wall thickness is up to three times as thick as said second wall thickness.

4. The catheter of claim 1,2 or 3, characterised in that the first and second passageways are of generally circular cross section.

5. The catheter of claim 4, characterised in that the passageways are of approximately equal area.

6. The catheter of any one preceding claim, characterised in that the first passageway comprises a negative pressure intake lumen and the second passageway comprises a positive pressure return lumen, and in that said first and second members are respective first and second predetermined lengths, said first member being longer than said second member at distal ends thereof.

7. The catheter of any one preceding claim, further characterised by a slip coating about a distal end of said first and second members.

8. The catheter of any one preceding claim, characterised in that the said first and second members form part of a first elongated segment (102), and a second elongated segment (103) extending proximally from said first segment and having said first and second longitudinal passageways extending therein.

9. The catheter of claim 8, characterised in that said second segment has a first predetermined cross-sectional shape.

10. The catheter of claim 9, characterised in that said first predetermined shape is generally elliptical.

11. The catheter of claim 8,9 or 10, further characterised by a collar positionable about said second segment and having a flange securable to tissue.

12. The catheter of claim 8,9,10 or 11, characterised in that the distal end of said first passageway is tapered.

13. The catheter of any one of claims 8 to 12, characterised in that said first and second segments comprise a biocompatible material having a predetermined durometer.

14. A collapsible dual-lumen hemodialysis catheter for percutaneous insertion through a smaller diameter introducer sheath, comprising: an elongated distal segment having a negative pressure intake lumen and a positive pressure return lumen extending longitudinally therein, said lumens having substantially equivalent cross-sectional circular areas and first and second walls, said first wall positioned about said intake lumen and having a first predetermined thickness and a first predetermined length, said second wall positioned about said return lumen and having a second predetermined thickness and a second predetermined length, said first thickness being approximately twice as thick as said second thickness, said first wall being a predetermined distance longer than said second wall at a distal end of said distal segment, said distal segment in a collapsed state having said second wall and said return lumen being collapsed about said first wall and said intake lumen and having a maximum cross-sectional dimension less than said smaller diameter introducer sheath, said distal segment also having a slip coating thereon; an elongated proximal segment extending proximally from said distal segment and having a generally elliptical cross-sectional shape, said lumens extending longitudinally through said proximal segment; and a moveable collar positioned about said proximal segment and having a flange with a suture hold therein.

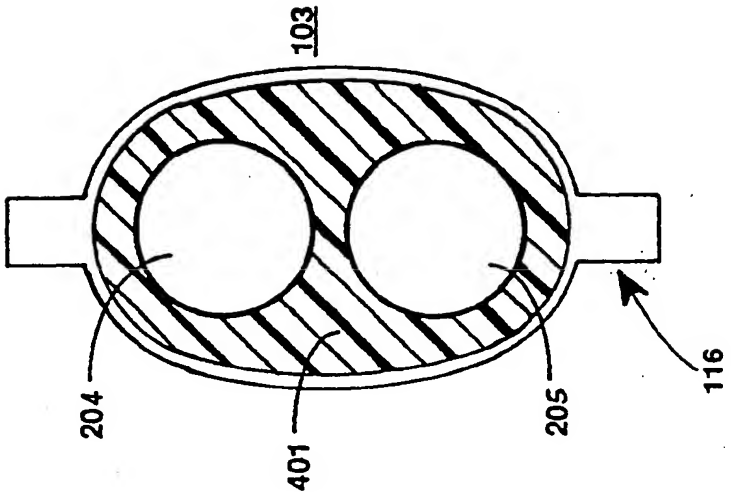

Fig. 4

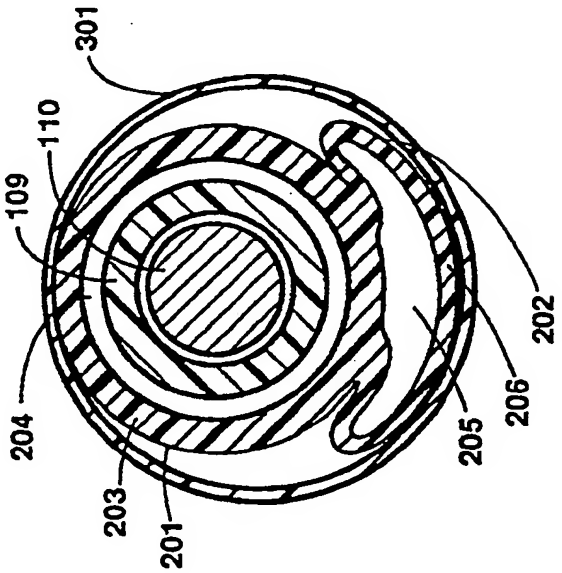

Fig. 3

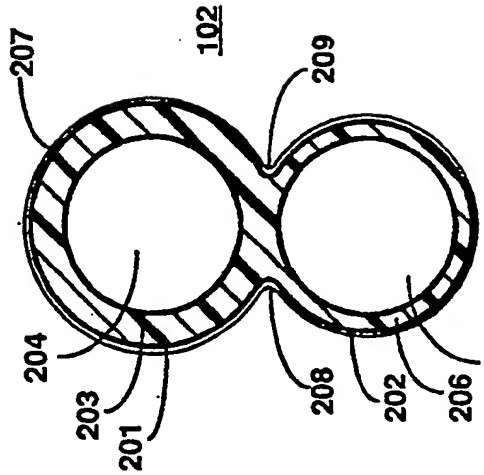

Fig. 2